REMARKS

Claims 1-5 have been amended. Claims 1-5 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite "detecting a change in the signal of the labeling material in the presence of the target, thereby detecting the target nucleic acid" so that the last step is in agreement with the preamble.

The Examiner states that claims 1-4 are indefinite because the claims may be interpreted different ways such as "(i) some of the first and second probes hybridize to each other and that some of the first probes hybridize to that target or (ii) that the first and second probes and the target all join together to form one hybridization complex" (Office Action, page 3, lines 3-5). Claims 1 and 4 have been amended to clarify that "a second probe [has] a second region that is complementary to at least a portion of the specific region of the first probe which is complementary to the target sequence". Accordingly, it is clear that the first probe is complementary to both the target and to the second region of the second probe. Support for the amendment is found in Figures 1 A & B.

The phrase "being capable of" has been deleted in claims 1 and 5.

Claims 1 and 4 have been amended to "wherein the nucleic acid of the second probe is labeled with a labeling material" to clarify which nucleic acid is labeled.

Regarding claim 3, "the fluorescence" has been changed to "a fluorescence". The phrase containing "the probes" has been deleted.

Claim 4 has been amended to be consistent with amendments to claim 1. It is respectfully submitted that "detecting a change in the signal" in claim 1 provides sufficient antecedent basis for "the detection of the change in the signal" in claim 4.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above grounds of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(a) & (e) over Weston

Claims 1 and 3-5 are rejected under 35 U.S.C. § 102 (a) and (e) as being anticipated by Weston, et al. (US Patent No. 6,391,593).

Weston, et al. teach a method of nucleic acid detection which employs two probes. The two probes hybridize to a target and thereby form a destabilizing moiety (such as a loop).

This contrasts with the claimed invention in which a first probe anneals either to a target or to a second probe. When the first probe anneals to a second probe, a loop is formed in the second probe. The second probe does not hybridize to the target. This differs from Weston, et al. as discussed below.

Weston, et al. teach that both probes hybridize to the target

The method of Weston, et al. requires that both of the first probe and the second probe hybridize with a target, while in the method of the presently claimed invention, the second probe only hybridizes with the first probe but does not hybridize with the target. That is, Weston requires that all three molecules hybridize in the presence of the target, while in Applicant's claimed invention, hybridization is to the first probe in the presence of the target, thus allowing detection of the signal from the second probe which is no longer quenched. In Applicant's claimed invention, the second probe which contains the loop, does not hybridize to the target, only to the first probe. See present claim 1 and compare Figure 1 of Weston, et al. to Figures 1 A & B of the present application.

Weston, et al. teach that the two probes do not hybridize to each other

Weston, et al. teach 'the first and/or second probe comprises a destabilizing moiety which cannot base pair with the reciprocal probe, thereby preventing hybridisation of the first and second probes in the absence of the sequence of interest." (see Weston, et al., Abstract, last line). In Weston, et al., the two probes do not hybridize to each other in the absence of the target. In contrast, the present claims recite "the loop region forming a loop when it is annealed with the first probe, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of the loop can be detected" (present claims 1 and 5). In the presently claimed invention, the loop forms when the two probes hybridize to each other in

the absence of the target. In Weston, the loop forms when both probes anneal to the target. Compare Figure 1 of Weston, et al. to Figures 1 A & B of the present application.

Regarding Figure 11C, although the Examiner states that Probe 2B' and Probe 1B are complementary to each other in at least two bases, one of ordinary skill in the art would recognize that Probe 2B' and Probe 1B will not hybridize to each other as these probes are complementary only in two bases which are non-contiguous. On the other hand, the present claims clearly recite that the two probes hybridize to each other in the absence of the target. In the Example of the present application, the first probe and the second probe have two complementary regions of at least 15-20 bases and hybridize with each other.

Only one of the probes of the claimed invention hybridizes to the target

Figure 11C of Weston, et al., like Figure 1, also differs in that both probes hybridize to the target, whereas Applicant's invention has hybridization only between probe 1 and the target, not probe 2 and the target (see Figure 1 A & B of the present application). Also note that the claims have been amended to specifically recite that the "first probe ... is complementary to the target sequence" (claim 1) which clarifies that it is the first probe which anneals to the target, not both probes as in the disclosure of Weston, et al.

The loop region of Weston, et al. only forms in the presence of the target

Weston, et al. teaches that the loop region forms only when the target is present and the two probes are annealed to the target (See Abstract and Figure 1 of Weston, et al). The present claims specify that the two probes anneal to each other to form the loop. As recited in claims 1 and 5, " a second probe ...[has a].. loop region forming a loop when it is annealed with the first probe, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of the loop can be detected". In the claimed invention, the loop forms when the two probes anneal to each other in the absence of the target.

Accordingly, Weston, et al do not teach all of the limitations of the present claims. Furthermore, the presently claimed invention is neither taught nor suggested by Weston, et al.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a) over Weston

Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Weston, et al. (US Patent No. 6,391,593).

For the reasons presented above, Weston, et al. neither teach nor suggest the invention as presently claimed. As claim 2 depends from claim 1 which is neither taught nor suggested by Weston, et al., claim 2 is also patentable over Weston, et al.

Applicant respectfully requests reconsideration and withdrawal of the rejection.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Aug 9, 2006

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